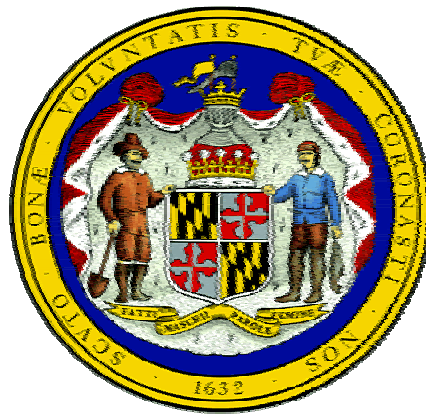


An Analysis and Evaluation of Certificate of Need Regulation in Maryland

Working Paper: Hospice Services

Summary and Analysis of Public Comments And Staff Recommendation



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I. Introduction

The Maryland Health Care Commission's working paper, titled *An Analysis and Evaluation of Certificate of Need Regulation in Maryland: Hospice Services*, was developed as one in a series of working papers examining major policy issues of the Certificate of Need process, as required by House Bill 995 (1999). The paper provides the basis for public comment on a series of potential alternative regulatory strategies:

- Option 1: Maintain Existing Certificate of Need Program Regulation
- Option 2: Expanded CON Program Regulation (Require CON or Exemption from CON to Close an Existing Program)
- Option 3: Retain CON Review, but Project Need and Consider Applications on a Regional, not a Jurisdictional Basis
- Option 4: Partial Deregulation-Regulate Only Inpatient Hospice Services and Deregulate Home-Based Services
- Option 5: Partial Deregulation - Regulate Only Sole/Two Provider Jurisdictions
- Option 6: Deregulation with Creation of a Data Collection and Reporting Model
- Option 7: Expand Ombudsman Role to Include Community-Based Services
- Option 8: Deregulation of Hospice with Expanded Licensure Standards and Oversight
- Option 9: Deregulation of Hospice Services from Certificate of Need Review

The objective of this working paper is to provide information to the Commission on whether changes are needed with respect to CON regulation of hospice services. The working paper was released for public comment at the September 15, 2000 meeting of the Maryland Health Care Commission. As of the date of this paper, thirteen (13) written comments have been received. Those public comments, submitted by the following organizations, are summarized in Part II. A Staff analysis of the public comments is provided in Part III. A Staff recommendation is provided in Part IV.

- Carroll County General Hospital
- Carroll Hospice, Inc.
- Chester River Home Care & Hospice
- GBMC HealthCare, Inc.
- Hospice Network of Maryland
- Hospice of Garrett County, Inc.
- Hospice of Prince George's Co., Inc.

- Hospice of Washington County, Inc.
- Howard County Board of Health
- Johns Hopkins Medicine
- MedStar Health
- MHA (The Association of Maryland Hospitals and Health Systems)
- Montgomery Hospice

II. Summary of Public Comments¹

Carroll County General Hospital (CCGH) strongly supports Option No. 1, maintaining the existing Certificate of Need program regulation. CCGH believes the CON requirement is the only way to ensure that a new provider of hospice services does not enter the market unless: (1) there is a need for a new provider, and (2) the provider satisfies a variety of criteria designed to ensure that its services will be comprehensive, non-discriminatory, and financially accessible; that the provider has the necessary commitments and ties to the community in which it proposes to provide services; and that the provider will not have an adverse effect on existing providers in the community. CCGH also notes that evidence presented to the General Assembly by the Hospice Network of Maryland in opposition to proposed legislation to deregulate hospice services introduced during the 1999 session showed that consumers in states with CON regulation of hospice receive 20 percent more hospice care than consumers in states without a CON requirement. CCGH believes that deregulating hospice services would have a negative impact on the health care system. The Hospital states that the removal of restrictions on market entry raises the possibility that supply will increase, thereby increasing the costs to existing providers, and potentially driving them out of the market. If the new providers, who may be national for-profit companies with little or no ties to the community, later decided to leave, the community will be left with unmet need. CCGH agrees with the study submitted to the General Assembly by the Hospice Network which found that increasing the number of programs would not increase the quantity or quality of hospice services. It will only divide limited resources among more, smaller and financially weaker programs. CCGH believes that the highest responsibility is to assure that hospice care is accessible and of high quality, that the patients receive the appropriate pain control and palliative services, including bereavement support, and that their families receive the necessary support. If there is any risk that deregulation would impair the achievement of this goal, CCGH believes it should be rejected.

Carroll Hospice, Inc. (Carroll Hospice) a related entity to CCGH, supports Option No. 1 because the CON requirement ensures that a new hospice agency cannot enter a community unless there is a need for it, and the agency satisfies the same quality, financial viability, cost, access and community ties criteria that the existing providers were required to satisfy. Carroll Hospice states that if there is no need for a new hospice agency, its establishment will have a negative impact on the health care system in the community because it will result in more programs and lower case loads for all programs. Carroll Hospice reports that, like other health

¹ A complete set of the written copies received on the Hospice Services Working Paper may be obtained by contacting the Division of Health Resources at (410) 764-3232.

care providers, it is having difficulties in finding and retaining qualified nurses and other staff. New hospice agencies in Carroll County would only exacerbate this problem and increase Carroll Hospice's employee costs. Increasing the number of programs will only divide limited resources and patients among more, smaller and weaker programs. Carroll Hospice is also concerned that opening the floodgates to new hospice programs may result in an influx of national, for-profit hospice providers in Maryland that lack the necessary ties and commitments to local communities.

Chester River Home Care & Hospice (Chester River) wishes to maintain the current framework of hospice programs and the current level of government oversight because it believes the system works. Chester River believes that the Certificate of Need policy prevents over saturation of hospice programs in high population areas and prevents low population areas from not having a hospice program. Therefore, anyone wishing hospice services has access to care, and local programs allow services to be "area specific". Chester River's outreach program provides home health services plus the standard hospice services of volunteer and supportive counseling. National for-profit hospices would not provide this type of personalized service. Chester River notes that the current Certificate of Need regulation is working and to eliminate it would upset the existing balance and possibly deny access to care. It believes that national for-profit hospices could move into the State and push big and small non-profits out of business. Consequently, Marylanders caring for Marylanders could be replaced by big businesses, and community support of local hospices would be eliminated. Chester River believes that profits from national hospices would not remain in Maryland, as has happened before with national home health agencies.

GBMC HealthCare, Inc. (GBMC) recommends that the Commission choose Option 9, noting that the effectiveness of CON as a means of controlling costs and service capacity has long been debated, and that CON to initiate hospice programs should be eliminated. GBMC provides hospice services through its subsidiary, Hospice of Baltimore, in both the inpatient and home setting. GBMC states that direct oversight and regulation of this service includes State licensure, Health Care Financing Administration (HCFA), the Office of the Inspector General, the Office of Health Care Quality, and the Public Health Administration. Indirect regulations include the Health Professional Boards and Commissions, the Maryland Department of Aging, the Officer of the Attorney General, and the Maryland Health Care Commission. With all of these regulations in place, GBMC believes there are sufficient checks in place to ensure the quality of care provided in hospice programs.

Hospice Network of Maryland (Hospice Network) strongly supports the case for retaining the current regulatory system for hospice services in the State of Maryland. Hospice Network believes the existing Certificate of Need structure has afforded great benefits to the development of hospice care in the State, and that nothing in the working paper or the study suggests that the alternatives formulated by the Staff will provide the same stability and support for end-of-life hospice care for Marylanders. Hospice care in Maryland has flourished under the existing regulatory structure and serves to enhance the availability and quality of care Marylanders enjoy at end-of-life. Most jurisdictions in the State are served by multiple hospice programs and, overall, hospice utilization in the State compares favorably with national averages. Existing hospice care in the State of Maryland works very well to meet the

end-of-life needs of the citizens of this State, according to Hospice Network. However, it suggests that more can be done in the areas of providing hospice care to residents of nursing facilities and attending to the needs of pediatric hospice patients and their families. Hospice Network believes that these areas deserve special attention and is working toward addressing these issues. Modifying or eliminating the Certificate of Need, according to the Hospice Network, will have the result that in addition to coping with the economic pressures imposed by a capitated reimbursement system and shorter lengths of stay, competing with other health care institutions for skilled staff, and with other charitable enterprises for fundraising dollars and volunteers, hospices will have to divert resources from providing care to the dying to compete with one another. This additional economic burden could have serious consequences for quality hospice care.

Hospice of Garrett County, Inc. recommends that the Maryland Health Care Commission endorse Option 1. Hospice of Garrett County, Inc. states that presently its daily census is ten to fifteen and it has no problem with increasing the number of patients served. According to the agency, Garrett County is the second largest county in Maryland with 662 square miles; however, it is small in population (approximately 29,000). Hospice of Garrett County, Inc. reports that it has nursing staff and volunteers located in all areas of the county who can be at a patient's home in minutes. The Hospice believes that emotional support and medical support must be available twenty-four hours a day. It states that another hospice could come in from West Virginia or Pennsylvania and only take ten patients. Hospice of Garrett County, Inc. believes that, in most cases, that would be taking money out of Maryland. It states that its system is working and requests that it not be changed.

Hospice of Prince George's Co., Inc. does not support maintaining the status quo. Rather, it supports the option of Expanding CON Program Regulation to include the closing of an existing program. In addition, Hospice of Prince George's Co., Inc. believes this should also be applied to mergers, with a review after the first six months to one year to ensure that services have not been depleted or that there are not program deficiencies. Hospice of Prince George's Co., Inc. also recommends adding some assessment of service capacity. Complete deregulation is not recommended, but Hospice of Prince George's Co., Inc. favors the idea of a moratorium while quality hospice program benchmarking is developed and implemented.

Hospice of Prince George's Co., Inc. believes that the unique issues of end-of-life care are not conducive to the monitoring of the ombudsman program. Although over 50% of hospice services are provided to seniors, the dying and end-of-life decisions and actions for the younger populations are more difficult to monitor. Hospice of Prince George's Co., Inc. believes that oversight by persons not committed to or competent in ensuring the goals of hospice care would add confusion and great frustration to hospice care delivery.

Considering CON applications on a regional basis, rather than a jurisdictional basis (Option 3), is vital to Hospice of Prince George's Co., Inc. with respect to after-hours and weekend care of hospice services. However, the Hospice does not support regulation of inpatient hospice services only (Option 4).

Regarding regulating only sole/two provider jurisdictions (Option 5), CON review regulations should be available as a method to meet unmet need. Hospice of Prince George's Co., Inc. further states that a lack of sufficient resources, operational expertise and program policy structure may leave a particular service area with insufficient choice to ensure that the highest level of hospice care is available.

Option 6, the reporting model, could best be done in collaboration with the licensure and survey process. Hospice of Prince George's Co., Inc. sites examples of the "Consumer Report Card" and "Peer Review Practice Standards" that are available through the American Hospice Foundation and the National Hospice and Palliative Care Organization.

The intent of Option 8 would be acceptable, but only with the understanding that much reform and support through staffing and funding must be made available to OHCQ. Hospice of Prince George's Co., Inc. believes that the current and past performance of OHCQ shows an agency that is already stretched beyond its capacity to do well in the licensing and survey practices for hospice programs. Without a major shift in practice and policy, it is doubtful that any measurable commitment to need or addressing capacity in each county would be realized.

Although Hospice of Prince George's Co., Inc. supports Option 2, (expanding CON program regulation to include the closing of an existing program), it appears to favor a combination of the various options.

Hospice of Washington County, Inc. requests that Option 1 (maintaining existing CON regulation) be maintained. The agency believes that in order to deliver comprehensive services, hospice programs must have an adequate client caseload per day to remain financially solvent. It states that the cost of caring for hospice patients varies from diagnosis to diagnosis and the point at which the patient enters the hospice program. Adding more hospice programs to an area through changes in the CON process will diminish the ability of the Hospice of Washington County, Inc. to offset costs. Hospice of Washington County, Inc. also states that changing the CON process will result in an increase in the number of hospices and the competition will prevent it from being able to manage the risk. Therefore, this will reduce the quality of care currently being provided to dying patients.

Howard County Board of Health supports Option 8 (deregulation of hospice with expanded licensure standards and oversight). It believes that this option will result in a decrease of the capital necessary to begin a project, but will still maintain oversight of licensure and quality. Howard County Board of Health believes strict standards of quality and their enforcement are important for hospice agencies.

Johns Hopkins Medicine supports Option 1 (maintain existing CON program regulation) for hospice services. The Agency feels that Option 1 is the best method of maintaining control over the number of organizations operating in the State of Maryland and the quality of care provided by those agencies. Johns Hopkins Medicine states that providing compassionate, responsive, high quality care requires significant investment in infrastructure to meet the requirements of regulatory and government agencies for providing and documenting care.

MedStar Health (MedStar) supports the continuation of existing Certificate of Need program regulations for hospice services. MedStar believes the CON program remains the State's most comprehensive regulatory tool for implementing health policies directed at: (1) ensuring that health care service development is consistent with State health goals and policies, (2) ensuring financial and geographic access of services to all Marylanders, (3) ensuring optimal quality among Maryland providers; and (4) ensuring that health care providers are accountable to the public. MedStar states that because of staffing, program requirements, and the per diem reimbursement structure, hospice programs require a minimum number of patients and an appropriate payer mix to operate effectively and efficiently. It believes the current CON model of regulation provides that safety net. MedStar believes that maintaining the current CON model of regulation will ensure that a new program will meet the minimum threshold requirements to operate a quality program.

The Association of Maryland Hospitals and Health Systems (MHA) supports Option 9, total deregulation of hospice services from CON without a moratorium on new or expanded services. MHA states that the 1997 BBA reductions and the free market are doing an efficient job of controlling market entry due to increased financial risk. According to MHA, hospice services are provided through a variety of entities that are regulated differently. For example, the State licenses hospice programs, home health care agencies, residential service agencies, nursing staff agencies, and nurse registries, but CON review is required only for hospice and home health. MHA believes that additional checks are already in place to ensure the quality of care provided in hospice programs since all of these programs require criminal background checks, and are subject to enhanced requirements for nursing assistants.

Montgomery Hospice strongly supports the opinion expressed by the Hospice Network of Maryland, that any regulatory change in the Certificate of Need program for hospice will be detrimental to the quality of hospice care, and therefore supports Option 1. It states that the supply and demand for skilled hospice labor (both paid and volunteer staff) and charitable dollars underscores the need for stable hospices.

Also important is the destabilizing nature of the inadequate reimbursement levels currently being paid by Medicare, which represent the vast majority of reimbursement for Maryland hospices. Montgomery Hospice states that the increases in Medicare reimbursement during most of the 1990's were not commensurate with the increases in the cost of either prescription medicine or the pay scales of registered nurses. In addition, Montgomery Hospice states that any change in the hospice market structure will exacerbate the destabilization that has already been made worse by the shortening lengths of stay.

Montgomery Hospice states that a final point for maintaining the existing CON regulation has to do with Medicare's 80/20 requirement for hospice services. In 1983, when the legislators were constructing the Hospice Medicare Benefit, there was a strong belief that hospice care in the United States should be delivered predominantly in people's homes. This was in contrast to the hospice model already developed in England. The 80/20 rule states that no more than 20% of a hospice's Medicare days may take place in an inpatient setting. Montgomery Hospice, with its 14-bed inpatient hospice, Casey House, must be vigilant that its

Hospice at Home service, the traditional home care hospice service, provides at least 80% of Montgomery Hospice's total Medicare days of care. Assuming that all 14 Casey House beds are occupied by Medicare patients, the Hospice at Home census on that same day must equal 56 Medicare patients. In its first year of operation, Casey House cared for nearly 250 patients and their families. The ability of this \$2.5 million facility to continue to care for the community will be jeopardized if outside hospices enter the market. Montgomery Hospice believes that the existing CON regulation should be maintained.

III. Staff Analysis of Public Comments

A. Option 1 - Maintain Existing Certificate of Need Program Regulation

The Certificate of Need program is designed to ensure that new health care services and facilities are developed only as needed, with the interests of the public in mind. CON review of proposed projects implements the policy goals and service-specific standards expressed in the State Health Plan. In addition, CON review allows the Commission to oversee, monitor, and respond to changes in hospice care services to make certain they have a positive impact on the health care system.

Without CON review as a means of regulating entry of new providers and service capacity into this market, the Commission would have no role in which to review new hospice services concerning their influence on the system of hospice care in Maryland, or to review service closures. Instead, market forces would guide decisions concerning access, and the role of competition would expand regarding cost and quality. For example, geographic access to care would be shaped by market forces, and the need to competition would drive provider decisions on cost and quality of care. The working paper and the public comments received address both the advantages and disadvantages of the current CON program and of deregulation, and are discussed below.

Public comments in support of maintaining existing CON regulation focus on the advantages of the program, including ensuring that a new hospice agency cannot enter a community unless there is a need for it, and the agency satisfies the same quality, financial viability, cost, access and community ties criteria that existing providers were required to satisfy. (CCGH; Carroll Hospice; Chester River; Hospice Network; Johns Hopkins Medicine; MedStar; and Montgomery Hospice.) Other providers' comments note that adding more hospice programs through changes in the CON process will diminish their ability to offset costs, will take money out of Maryland, and will drive some hospices out of the market. (CCGH; Carroll Hospice; Chester River; Hospice of Garrett County, Inc.; Hospice of Washington County, Inc.)

Hospice Network suggests that hospice care in Maryland has flourished under the existing regulatory structure and believes the existing CON structure has afforded great benefits to the development of hospice care in Maryland.

B. Option 2 - Expanded CON Program Regulation (Require CON or Exemption from CON to Close an Existing Program)

The working paper's option to require Commission review and approval of service closures, rather than simple notification would allow the Commission to determine whether one program's failure was an isolated incident or whether it represented a warning of problems which could affect the entire provider community. Comments from Hospice of Prince George's Co., Inc. express its support for this option. In addition, the agency believes the regulation should also be applied to mergers. Further, Hospice of Prince George's Co., Inc. believes a review should take place after the first six months to one year to ensure that services have not become deficient.

C. Option 3 - Retain CON Review, but Project Need and Consider Applications on a Regional, not a Jurisdictional Basis

This option would retain CON regulation, but would modify the Commission's consideration of new or expanded agencies to a regional rather than a jurisdiction approach. Hospice of Prince George's Co, Inc. states that considering CON applications on a regional basis, rather than a jurisdictional basis, would be beneficial in after-hours and weekend care delivery of hospice.

D. Option 4 - Partial Deregulation-Regulate Only Inpatient Hospice Services and Deregulate Home-Based Services

Under this option of the working paper, CON would be partially deregulated, but licensure oversight would continue. Hospice of Prince George's Co., Inc. does not support regulation of inpatient only.

E. Option 5 - Partial Deregulation - Regulate Only Sole/Two Provider Jurisdictions

Since the addition of another program into a small market has the potential to destabilize and drive out of business one or both of the existing entities, the working paper offered this option. The option supports the continuation of CON for entry into small markets and could require Commission review of proposed closures, but would deregulate other jurisdictions from CON review.

There was no support for this option. CON review regulations should be in place as a method to meet quality control according to the Hospice of Prince George's County, Inc. The agency states that the most community driven, community supported program may not adequately offer or assure the highest quality of hospice services.

F. Option 6 - Deregulation with Creation of a Data Collection and Reporting Model

Under this option, the focus of government would shift to providing information in order to promote quality health services. Performance cards, or "report cards" would inform consumers and could improve the performance of health care providers.

There was no support for this option. Hospice of Prince George's Co., Inc. states that timely, concretely measurable service delivery outcomes and a reporting model to assess need is the most unique way to ensure quality health services.

G. Option 7 - Expand Ombudsman Role to Include Community-Based Services

Under this option, the responsibilities and authority of the county long term care ombudsman now only charged with consumer advocacy in nursing home care, would be expanded to include community-based services including hospice. Ombudsmen would develop a system to investigate complaints and identify system-wide deficiencies in Maryland. Additional funding and staffing would be required to implement this option.

There was no support for this option. Hospice of Prince George's Co., Inc. states that the unique issues of end-of-life care are not conducive to the monitoring of the ombudsman program. Because hospice issues differ greatly from the types of issues that are familiar to those in the ombudsman program, this agency believes it could be difficult for ombudsmen to provide the same level of scrutiny regarding matters concerning hospice.

H. Option 8 - Deregulation of Hospice with Expanded Licensure Standards and Oversight

The working paper's option of shifting the role of government oversight from regulating market entry and exit to monitoring the ongoing performance of providers would require that OHCQ enhance existing licensure standards. Comments from Hospice of Prince George's Co., Inc. found the intent of the option acceptable, but only with the understanding that OHCQ secure additional staffing and funding, to support the additional demands on staff resources and time.

In favoring this option, the Howard County Board of Health notes that strict standards of quality and their enforcement are important for hospice agencies, and maintains that this approach will maintain oversight of license and quality while decreasing the capital required to initiate a project.

I. Option 9 - Deregulation of Hospice Services from Certificate of Need Review

MHA states that start-up of hospice programs requires a minimal capital investment, and therefore, their failures have little cost implication for the system. Further, MHA believes that CON applications in the past have been routinely processed and approved, but not without considerable expense.

Comments from Hospice of Prince George’s County, Inc. do not support maintaining the current CON review. In addition, the agency would not support complete deregulation in any manner, but would recommend the idea of a moratorium while quality hospice program benchmarking is developed and implemented.

A letter from GBMC HealthCare, Inc. describes two reasons for eliminating CON laws for hospice services. First, GBMC states that the effectiveness of CON as a means of controlling costs and service capacity has long been debated. Second, GBMC believes that sufficient oversight is already available by various agencies to ensure the quality of care provided in hospice programs.

The following table summarizes the options that commenters supported:

Table 1
Options Supported in Public Comments

Facility	REGULATE			DEREGULATE					
	Option 1	Option 2	Option 3	Option 4	Option 5	Option 6	Option 7	Option 8	Option 9
Carroll County General Hosp.	X								
Carroll Hospice, Inc.	X								
Chester River	X								
GBMC HealthCare, Inc.									X
Hospice Network of Md.	X								
Hospice of Garrett County, Inc.	X								
Hospice of PG County, Inc. ²		X							
Hospice of Washington Co., Inc.	X								
Howard Co. Board of Health								X	
Johns Hopkins Medicine	X								
MedStar Health	X								
MHA									X
Montgomery Hospice	X								
Total:	9	1	0	0	0	0	0	1	2

IV. Staff Recommendation

Issues raised by the regulation of hospice services are extremely complicated. Persuasive arguments can be made on both sides of the policy debate regarding CON regulation of hospice services. As shown in Table 1, however, most commenters recommend retaining CON regulation of hospice services. Having reviewed and evaluated the entire framework of government oversight of hospice services in Maryland, Staff recommends that Option 1, maintaining existing CON regulation.

Among the overwhelming majority of hospice providers as well as their State professional network, a strong consensus credits the existing Certificate of Need structure with providing stability and support for end-of life hospice care in Maryland. Under the current CON, most jurisdictions in the State are served by several hospice programs. Additional

² Hospice of PG Co., Inc. states it does not support Options 1, 7, and 9. It would find Option 8 acceptable if OHCQ received additional staffing and funding.

reasons that Staff recommends the continued CON regulation of hospice services reflect some consensus and considerations voiced by the State's hospice industry:

- Because volunteers are essential elements in home-based hospice care, many agencies compete for their time and commitment. Continued regulation through CON would ensure that the supply of qualified volunteers could meet the demand of the number of certified hospice providers.
- The majority of hospices in Maryland are non-profit agencies; therefore, hospices rely greatly on the generosity of local donors for fundraising dollars. Increased competition for community donations would increase the already considerable pressures of securing economic support for hospice services.

As Staff pointed out in the working paper, and as the majority of the commenters agreed, the supply of existing hospice care providers is meeting the end-of-life needs of the citizens of Maryland. Staff's recommendation to retain CON regulation of hospice services would not preclude working with the Department's Office of Health Care Quality to expand State licensure requirements to allow for more frequent surveys and incorporate other ongoing quality and access measures, that reflect the distinct character of this service in Maryland. Retaining the authority to consider new hospice providers only when additional need warrants will help maintain the stability of a mission-driven, mostly not-for-profit provider community, heavily dependent on its volunteers and the experience of its professional staff.